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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,229	04/08/2004	Tara Ziolo	5490E-000365	9402
27572 7590 04/03/2007 HARNESSE, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/821,229

Applicant(s)

ZIOLO ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 37-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-39 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Konieczynski et al. (US Pub. 2004/0127899 A1).

Konieczynski et al. disclose a bone fixation apparatus comprising a bone fixation plate (Fig. 1A, ref. 20) having a fixation hole (Fig. 1C, ref. 28), the fixation hole having a first diameter (Fig. 1C, between flanges just above ref. 70) in a plane generally parallel to an upper surface of the bone fixation plate (Fig. 1C); and a modular bone fixation fastener (Fig. 1B, ref. 40) including a shaft member (Fig. 1B, ref. 62) defining a shaft axis and an expandable (paragraph 0073) annular head member (Fig. 1C, ref. 70) carried by the shaft member, the expandable head member being rotatable about the shaft axis relative to the shaft member between a first position and a second position, such that in the first position the expandable head member has a maximum diameter that is smaller than the first diameter of the fixation hole, and in the second position the expandable head member has a maximum diameter that is greater than the first diameter. Since the expandable head member is resilient (paragraph 0089), the

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expandable head member can be bent into a configuration where the maximum diameter is less than the first diameter of the fixation plate, and it can also have a diameter which is larger than the first diameter of the fixation plate (Fig. 1C, ref. 70).

The expandable head member has a generally spherical outer surface (Fig. 1A, ref. 70).

The fixation hole is generally spherical (Fig. 1C, ref. 28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konieczynski et al. (US Pub. 2004/0127899 A1) in view of Sutter et al. (US Pat. 4,388,921).

Konieczynski et al. disclose a bone fixation apparatus comprising: a bone fixation plate (Fig. 1A, ref. 24) having a fixation hole (Fig. 1A, ref. 30); and a modular bone fixation fastener (Fig. 1A, ref. 54) received in the fixation hole (Fig. 1A), the bone fixation fastener including a shaft member (Fig. 1A, ref. 62) and an expandable (paragraph 0073) annular head member (Fig. 1A, ref. 70) defining an internal surface (Fig. 1A, ref. 72), the shaft member defining a circumferential outer cam at a first end (Fig. 10E, ref. 450), the outer cam in the form of a continuous curve of continuous slope and variable radius, since the cam's surface is continually curving with respect to a radius drawn

from the central axis of the cam outward to the cam's surface (Fig. 10E), an internal surface of the head member (Fig. 1A, ref. 72), the outer cam circumferentially mating with the inner cam of the head member, such that upon rotation of the head member relative to the shaft member, the head member radially expands to prevent back out of the shaft member relative to the bone fixation plate (paragraph 0084). The fixation hole includes a countersunk portion receiving at least a portion of the expandable head member of the bone fixation fastener (Fig. 4A, ref. 128). The inner surface of the fixation hole is spherical (Fig. 1A, ref. 30) and engages a spherical outer surface of the head member (Fig. 1A, ref. 46), such that the fixation fastener can be positioned at a plurality of angles relative to the plate before locking. The bone fixation plate includes a viewing window (Fig. 1A, ref. 26). The bone fixation plate is a spinal fixation plate for securing first and second vertebral bodies relative to one another (Fig. 1A). The bone fixation plate is a spinal fixation plate for securing at least three vertebral bodies relative to one another (Fig. 1A). The bone fixation apparatus further comprises at least one viewing window (Fig. 1A, ref. 26). The bone fixation apparatus comprises at least one aperture receiving an anchoring fastener (Fig. 1A, aperture surrounding ref. 68). The bone fixation apparatus comprises at least another fixation hole receiving another modular fixation fastener (Fig. 1A, ref. 18). Konieczynski discloses an insertion and removal tool (paragraph 0075), the tool comprising a first driver attached to a handle (paragraph 0075), the driver adapted to engage the head member for rotation of the head member relative to the shaft member. The tool comprises a second driver (Fig. 3)(paragraph 0080) adapted to engage the shaft member for inserting and removing the shaft

member to and from a bone portion when the fixation member is not locked. The head member radially expands against an inner surface of the fixation hole to pressure-lock the fixation fastener and thereby prevent relative movement between the fixation fastener and the plate (paragraph 0089). The head member and the fixation fastener are cooperatively configured to provide a first mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is adjustable relative to the plate and a second mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is arrested relative to the plate.

Konieczynski et al. disclose a bone fixation apparatus comprising: a bone fixation plate (Fig. 1A, ref. 24) having a fixation hole (Fig. 1A, ref. 30); and a modular bone fixation fastener (Fig. 1A, ref. 54) received in the fixation hole, the bone fixation fastener comprising: a shaft member (Fig. 1A, ref. 62) having a head (Fig. 1A, ref. 46) having a first end (Fig. 1A, end of ref. 46), the first end defining a circumferential multi-radius continuously curved outer surface (Fig. 10E, ref. 450), the outer surface having continuous slope and defining a shaft cam lobe (Fig. 10E, ref. 450); and an expandable (paragraph 0073) head member (Fig. 1A, ref. 70) having an inner opening (Fig. 1A, opening through central portion of ref. 70) defining an internal circumferential surface (Fig. 1A, ref. 72). The head member radially expands against an inner surface of the fixation hole to pressure-lock the fixation fastener and thereby prevent relative movement between the fixation fastener and the plate (paragraph 0089). The inner surface of the fixation hole is spherical and engages a spherical outer surface of the

head member, such that the fixation fastener can be positioned at a plurality of angles relative to the fixation plate when the head member is not expanded (Fig. 1A, ref. 70). The head member and the fixation fastener are cooperatively configured to provide a first mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is adjustable relative to the plate and a second mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is arrested relative to the plate.

Koniiecznski et al. do not disclose the internal surface of the head member defining a circumferential inner cam in the form of a continuous curve of continuous slope and variable radius and devoid of kinks; the inner cam has at least one lobe; the inner cam has a plurality of lobes; the inner cam includes three equidistant lobes; an internal circumferential surface in the form of a multi-radius continuously curved inner surface, the inner surface having continuous slope and being devoid of kinks and defining a head cam lobe; and the inner head surface defining a plurality of mating cam lobes.

Sutter et al. disclose a fixation plate (Fig. 15, ref. 207) and a fixation fastener (Fig. 15, ref. 209) and a head member (Fig. 15, ref. 211) with a circumferential inner cam (since the internal wall is eccentric, column 4, lines 49-51), in the form of a continuous curve of continuous slope (Fig. 15, ref. 211d) and variable radius (since the internal wall is eccentric, column 4, lines 49-51). The inner cam is devoid of kinks (Fig. 15). The eccentric part of the head member (the wider portion of the head member on the right side of ref. 211) can be considered to be a lobe. The lobe is useful in allowing a

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surgeon to turn the screw and compress bone fragments together (Fig. 3)(column 5, lines 34-54).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the internal surface of the head member of Konieczynski et al. with the with a circumferential inner cam, in the form of a continuous curve of continuous slope and variable radius and being devoid of kinks, all as taught by Sutter et al., in order to allow a surgeon to turn the screw and compress bone fragments together (Sutter et al., column 5, lines 34-54 and Fig. 3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the apparatus of Konieczynski et al. in view of Sutter et al. having a plurality of lobes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments with respect to claims 1-21 and 37-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

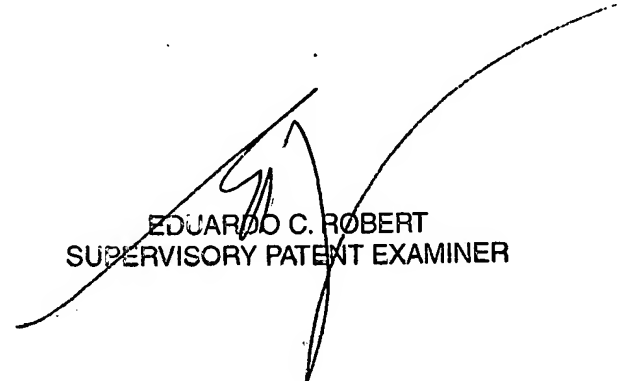
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER